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July 13, 2022

VIA CM-ECF

The Honorable Richard G. Andrews
United States District Court
For the District of Delaware
844 North King Street
Wilmington, DE 19801

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Re: *Allergan USA, Inc. et al. v. Sun Pharm. Indus. Ltd.*, C.A. No. 19-1727-RGA
Letter Regarding Defendants' Motion for Leave to File Summary Judgment

Dear Judge Andrews:

In this Hatch-Waxman patent infringement case, Defendant Sun Pharmaceutical Industries, Ltd. respectfully requests leave to file a motion for summary judgment as to a single discrete issue of law that would resolve all disputes concerning two asserted patents: whether Plaintiff Allergan can assert a doctrine of equivalents (“DOE”) theory that directly contradicts this Court’s claim construction.

All asserted claims of these two formulation patents require the excipient “colloidal silica.” This Court construed “colloidal silica” to be “distinct from the amount of [colloidal silica] present in the silicified microcrystalline cellulose” (“SMCC”), which is a separately recited excipient in all the asserted claims. D.I. 140 at 14. Put simply, the Court held that any colloidal silica in SMCC does not meet the limitation that separately requires colloidal silica.

On June 17, 2022, Allergan served an expert report that includes infringement opinions under a DOE theory that directly contradicts this claim construction. According to Allergan’s theory, Sun’s ANDA products do not literally infringe these two patents, but they still infringe under the DOE because [REDACTED] Ex. A, Berkland Infringement Report at ¶ 109. In other words, Allergan is asserting a DOE theory that would vitiate the Court’s claim construction. This theory fails as a matter of black-letter law and should be rejected on summary judgment. *See Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014) (“No reasonable jury could find equivalence [where] doing so would require a determination” that the alleged equivalent is “the very thing that the construction [] excludes.”) (affirming summary judgment of no infringement).

Entertaining an early summary judgment motion of non-infringement on this straightforward legal question will significantly reduce the issues to be tried. Sun has agreed to stipulate to infringement of any remaining claims that do not require colloidal silica in the formulation. Thus, trial would be limited to issues of invalidity and unenforceability.



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I. Background – Sun’s ANDA Products Do Not Literally Infringe Because They Do Not Comprise a Distinct Amount of [REDACTED]

As the Court may recall from recent briefing submitted in connection with Allergan’s pending motion to dismiss Sun’s unclean hands defense (D.I. 354, 355, 358, and 363), the six patents asserted against Sun all claim formulations comprising eluxadoline and certain recited excipients. The initial suit asserted two patents, U.S. Patent Nos. 9,675,587 (the “’587 Patent”) and 10,188,632 (the “’632 Patent”), which were the only formulation patents listed in the FDA’s Orange Book at the time Sun filed its ANDA. The ’587 and ’632 Patents require “colloidal silica” as a separately recited limitation. The remaining four patents—U.S. Patent Nos. 11,007,179, 11,090,291, 111,160,792, and 11,311,516—were all prosecuted and obtained during the litigation and include claims that do not require colloidal silica (also referred to as colloidal silicon dioxide).

In December 2020, this Court held a *Markman* hearing to construe the claims of the originally asserted ’587 and ’632 Patents, including two terms of particular relevance here—“silicified microcrystalline cellulose” or SMCC (a filler) and “colloidal silica” (a glidant). ’587 Patent at Table 1. Both excipients are required by every asserted claim in these two patents. The parties did not dispute that SMCC comprises colloidal silica. Thus, the Court construed SMCC as a “a coprocessed combination of microcrystalline cellulose (98%) and colloidal silicon dioxide (2%).” D.I. 140, *Markman* Order at 9.

As noted, however, the asserted claims of the ’587 and ’632 Patents also recite “colloidal silica” as a limitation separate from “silicified microcrystalline cellulose.” The Court recognized that, “[a]t the heart of [the *Markman*] dispute are Defendants’ efforts to distinguish the colloidal silicon dioxide present in the compound from the colloidal silicon dioxide that interacts with the microcrystalline cellulose to create silicified microcrystalline cellulose.” *Id.* at 14. In construing “colloidal silica,” this Court made “clear that the colloidal silicon dioxide in the silicified microcrystalline cellulose cannot count” towards satisfying the distinct limitation for colloidal silica. *Id.* at 15. Thus, this Court held (with Allergan’s stated agreement) that the term requires “*an amount of [colloidal silica] distinct from the amount of [colloidal silica] present in the silicified microcrystalline cellulose.*” *Id.* at 14 (emphasis added).

Following this *Markman* order, Allergan “[a]dmitted” that “Sun’s ANDA Products do not literally infringe any claim” of the ’587 and ’632 Patents “under the Court’s claim constructions.” Ex. B, Allergan’s Responses to First Set of RFAs at 2. Allergan nonetheless pursued two infringement strategies.

First, Allergan began prosecuting broader pop-up patents claiming formulations lacking colloidal silica, which Allergan did not invent. This conduct forms the basis of Sun’s unclean hands defense at issue in Allergan’s pending motion to dismiss. D.I. 354, 355, 358, and 363.

Second, Allergan contends that the colloidal silica present in the SMCC meets the limitation for colloidal silica under a DOE theory. As discussed below, this theory fails as a matter of law because it vitiates the court’s claim construction requiring colloidal silica be “distinct from



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the amount of [colloidal silica] present in the silicified microcrystalline cellulose.”

II. Argument – Allergan’s Theory of Infringement Under DOE Vitiates the Court’s Claim Construction.

Allergan’s infringement expert, Dr. Berkland, sets forth his opinions in support of Allergan’s theory of infringement under the doctrine of equivalents:

To summarize, ***SMCC is coated with colloidal silica***; the colloidal silica is chemically unchanged as result of its co-processing and association with microcrystalline cellulose. ***SMCC will perform a glidant function in the same way as colloidal silica added separately***. The surface of SMCC is coated with colloidal silica, and the effects of glidants, in promoting the flow of the powder blend, are observed at the surfaces of the particles of the powder blend as they move relative to each other.

Ex. A, at ¶ 109 (citation omitted) (emphasis added). Said another way, Dr. Berkland opines that the colloidal silica present in SMCC functions equivalently to the claimed limitation for colloidal silica. But the Court held that such colloidal silica in the SMCC cannot be used to satisfy the “colloidal silica” limitation—instead, it must be “distinct from the amount of colloidal silicon dioxide present in the silicified microcrystalline cellulose.” D.I. 140 at 14.

The Federal Circuit has held that “[i]f a theory of equivalence would vitiate a claim limitation,[] then there can be no infringement under the doctrine of equivalents as a matter of law.” *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998) (“Such a result is impermissible under the all-elements rule of *Warner-Jenkinson*.”) (citation omitted). “[T]he doctrine of equivalents may not be applied” “[w]hen the substitution of one feature [] for another into an element of the accused product places it outside the scope of the recited claim element.” *Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1337–39 (Fed. Cir. 2004) (affirming JMOL of noninfringement under DOE). “[T]he principle … that the doctrine of equivalents cannot be employed in a manner that wholly vitiates a claim limitation” is “a corollary to the ‘all limitations’ rule.” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1347 (Fed. Cir. 2001) (quoting *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996)) (affirming summary judgment of noninfringement under DOE).

The principle of vitiation is particularly relevant where “[n]o subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation into the claim.” *Sage Prod., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997) (affirming summary judgment of noninfringement under DOE). Such rationale rings true here, where the patentee surrendered during prosecution of the ’587 and ’632 patents broader claims



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requiring only one of SMCC, colloidal silica, or other named excipients.¹

In sum, the issue of noninfringement is ripe for summary judgment practice because [REDACTED] [REDACTED] that is “distinct” from silicified microcrystalline cellulose, and Allergan does not contend otherwise. The only question for the Court is whether Allergan’s DOE theory vitiates the Court’s construction and is barred by the “all elements” rule. This is a discrete legal issue that could narrow the trial. Sun thus respectfully asks the Court for leave to file a motion for summary judgment of noninfringement.

Additionally, Sun respectfully requests that the Court order Plaintiffs to file their response to this request within one week of the filing of this letter. Should the Court grant Sun’s request, Sun is prepared to file its motion and opening brief within two business days after such leave is granted, and Sun will file its reply brief in support of its motion within four business days after Plaintiffs file their opposition brief.

Respectfully,

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)

cc: Clerk of the Court (via CM-ECF)
Plaintiffs’ Counsel of Record (via electronic mail)

¹ If necessary, Sun would be prepared to show at trial that DOE is barred by prosecution history estoppel. *See* D.I. 129, Joint Claim Construction Brief at 46-47 (discussing narrowing amendment) (citing ’587 prosecution history, Mar. 17, 2015 Claims (D.I. 101-2, Ex. 11) at 2; ’587 prosecution history, Mar. 17, 2015 Response (D.I. 101-2, Ex. 11) at 8.).